

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the directions for use appearing therein "For Use in Menopausal Symptoms 5,000 units to 25,000 units Intramuscularly 2 or 3 Times Weekly" failed to disclose the amount of the drug to be injected.

DISPOSITION: May 25, 1950. Default decree of destruction.

3172. Misbranding of homeopathic tablets. U. S. v. 45 Cartons, etc. (F. D. C. No. 28476. Sample Nos. 49659-K to 49661-K, incl.)

LABEL FILED: December 21, 1949, District of Colorado.

ALLEGED SHIPMENT: On or about January 29, July 1, and October 17, 1949, by Ehrhart & Karl, from Chicago, Ill.

PRODUCT: 45 cartons of *homeopathic tablets*, 6 cartons of *Homeopathic Compound Tablets*, and 2 cartons of *Plain Bioplasma Celluids tablets* at Denver, Colo., in possession of the Colorado Mineral Health School.

Quantities of the tablets had been repackaged by, and were in possession of the Colorado Mineral Health School, together with a number of circulars, printed locally entitled "A Few Facts Worth Knowing," which accompanied the repackaged tablets.

LABEL, IN PART: (Cartons) "Tablet Triturates Homeopathic Private Formula No. * * * 1 Lb." and "Homeopathic Compound Tablets Private Formula No. 222a 6X * * * Added 50 Units Vitamin B₁ per tablet 1 Lb. * * *"; (packages) "A Biochemic Homeopathic Product Calcium Phosphate * * * No. 2 [or "Calcium Sulphate * * * No. 3," "Iron Phosphate * * * No. 4," "Potassium Chloride * * * No. 5," "Potassium Phosphate * * * No. 6," "Potassium Sulphate * * * No. 7," "Magnesium Phosphate * * * No. 8," "Sodium Phosphate * * * No. 9," "Sodium Phosphate * * * No. 10," "Sodium Sulphate * * * No. 11," "Silicea * * * No. 12"] Celluids," "A Biochemic Homeopathic Product Plain Bioplasma Celluids * * * A Combination of all the 12 minerals, prepared according to Bio-Chemistry Therapy * * * Each tablet contains 12 Minerals Potensised to the consistency of the blood according to Bio-Chemic Theory," and "A Biochemic Homeopathic Product Bioplasma Celluids * * * A Combination of all the 12 minerals, prepared according to Bio-Chemistry Therapy. * * * Each tablet contains not only the Mineral, but there has been added, 50 units of Vitamin B₁, to each tablet."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles in the 45-carton, 6-carton, and 2-carton lots failed to bear adequate directions for use since they failed to bear any directions for use. The articles in such lots were misbranded in the above respect when introduced into and while in interstate commerce.

Misbranding, Section 502 (a), certain statements on the labels of the repackaged tablets and in the circulars accompanying such tablets were false and misleading since the articles were not capable of fulfilling the promises of benefit stated and implied by the statements. These statements represented and suggested:

That the *Celluids No. 2 tablets* would be beneficial for digestion, broken or weak bone structure, discharge of albumen, and after wasting illness; and that the tablets would be efficacious in the cure, mitigation, and treatment of Bright's disease, consumption, and catarrh;

That the *Cellaids No. 3 tablets* would be beneficial in the discharge of thick, yellow matter, which is sometimes mixed with blood; that the tablets would be effective to remove waste matter from the body through the liver route; and that they would be effective in the cure, mitigation, and treatment of boils, carbuncles, abscesses, pimples, and all pus conditions of the surface, not deep seated;

That the *Cellaids No. 4 tablets* would be beneficial in the treatment of feverish conditions, inflammation, burns, scalds, and cuts; and that the tablets would be effective in the treatment and prevention of congested conditions of any kind or place, such as inflammation, coughs, colds, chills, and pneumonia;

That the *Cellaids No. 5 tablets* would be beneficial in the treatment of the discharge of gray, thick phlegm, deep cough, swollen tonsils, and all soft swellings; that the tablets would be efficacious in the treatment and prevention of tonsillitis, scarlet fever, smallpox, measles, and chicken pox; that they were needed in the treatment of all burns, scalds, bruises, or any swollen conditions; and that they were needed by all growing children;

That the *Cellaids No. 6 tablets* would be beneficial in the treatment of nervous disorders, palpitation, difficult breathing, decay, and offensive discharges; that the tablets would build the gray nerve matter or the thinking part of the brain; that they would be effective in the treatment and prevention of deficient brain power, nervousness, lack of energy, paralysis, palpitation of the heart, sleeplessness, and insanity; and that they would be efficacious in the prevention of many cases of suicide;

That the *Cellaids No. 7 tablets* would be beneficial in the treatment of disturbed respiration and feverish conditions with dry skin; and that the tablets would open the pores of the skin and relieve the body of a hot, dry, and feverish condition;

That the *Cellaids No. 8 tablets* would be beneficial in the treatment of sharp, piercing pains; cramping, convulsions, and spasmodic conditions of any kind;

That the *Cellaids No. 9 tablets* would be beneficial in the treatment of simple colds, excessive flow of urine, watery eyes, sunstroke, and insect bites; and that the tablets would be effective in the cure, mitigation, and treatment of dropsy, hay fever, fresh colds, and sneezing;

That the *Cellaids No. 10 tablets* would be beneficial in the treatment of excess acid, sour stomach, nausea, discharge of creamy, yellow substance, and sour-smelling perspiration; that the tablets would prevent the thickening of bile and mucous; that they would be efficacious in the treatment and prevention of jaundice, colic, and bilious headache; and that they would be efficacious in the treatment of gout, acute and chronic rheumatism, and acid conditions;

That the *Cellaids No. 11 tablets* would be beneficial in the treatment of excess bile, chilly and feverish conditions, and yellow skin and eyeballs; and that the tablets were needed in the treatment of all diseases known as "colera," yellow fever, chills, fever and ague, flu, la grippe, and jaundice conditions;

That the *Cellaids No. 12 tablets* would be beneficial in the treatment of swellings of suppurative nature, discharge of thick, profuse pus, night sweats, and offensive feet; that the tablets would be efficacious in the removal of pus and waste accumulations from the body; that they would ripen boils, abscesses, and carbuncles, and would remove all traces of pus; and that they would be efficacious in the treatment of locomotor ataxia, constipation, asthma, and ulcers;

That the *Cellaids tablets Nos. 2 through 12* were necessary for the proper function of the body; and that the tablets alone, or in combination with proper food, would enable one to master any disease;

That the *Plain Bioplasma Cellaids tablets*, and the *Bioplasma Cellaids tablets containing vitamin B₁* would be beneficial as a general tonic.

DISPOSITION: March 17, 1950. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3173. Adulteration of *Ru Nitrol tablets*. U. S. v. 1 Drum * * *. (F. D. C. No. 28987. Sample No. 72241-K.)

LIBEL FILED: April 20, 1950, Northern District of Ohio.

ALLEGED SHIPMENT: On or about March 1, 1950, from Detroit, Mich. This was a return shipment.

PRODUCT: 1 unlabeled drum containing 18,000 *Ru Nitrol* tablets at Cleveland, Ohio.

LABEL, IN PART, WHEN ORIGINALLY SHIPPED: "Phenobarbital $\frac{1}{4}$ Gr. — Mannitol Hexanitate $\frac{1}{2}$ Gr., Rutin 20 Mg."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported to possess. (Analysis showed that the article contained less than the stated amounts of phenobarbital, mannitol hexanitate, and rutin.)

DISPOSITION: July 28, 1950. Default decree of condemnation and destruction.

3174. Adulteration of *Semestrin*. U. S. v. 10 Packages * * *. (F. D. C. No. 28992. Sample No. 55890-K.)

LIBEL FILED: On or about April 25, 1950, Western District of Missouri.

ALLEGED SHIPMENT: On or about August 12 and November 15, 1949, by the S. E. Massengill Co., from Bristol, Tenn.-Va.

PRODUCT: 10 packages, each containing 6 1-cc. ampuls, of *Semestrin* at Kansas City, Mo. Examination showed that the product contained, per 1 cc., materially less than 2 milligrams of highly purified estrogenic substance from the urine of pregnant mares, consisting mainly of estrone, with small amounts of other accompanying estrogens; and that the product possessed a potency, per 1 cc., materially less than 20,000 International Estrone Units.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 20,000 International Units of estrone (2 milligrams of estrogenic substance) per cubic centimeter.

DISPOSITION: June 22, 1950. Default decree of destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3175. Misbranding of *La Sierra Brand Formula M-G 5 (Male) tablets*. U. S. v. 3 Bottles, etc. (F. D. C. No. 29069. Sample No. 67655-K.)

LIBEL FILED: April 21, 1950, District of Colorado.

*See also Nos. 3170. 3172.